Symptoms, unmet needs, psychological well-being and health status in prostate cancer survivors

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Symptoms, unmet needs, psychological well-being and health status in prostate cancer survivors: implications for redesigning follow-up

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Abstract

Objective

To explore ongoing symptoms, unmet needs, psychological wellbeing, self-efficacy and overall health status in prostate cancer survivors. **Subjects/patients and Methods**

An invitation to participate in a postal questionnaire survey was sent to 546 men, diagnosed with prostate cancer 9 – 24 months previously at two UK cancer centres. The study group comprised men who had been subject to a range of treatments: surgery, radiotherapy, hormone therapy and active surveillance. The questionnaire included measures of prostate-related quality of life (EPIC-26); unmet needs (SCNS SF34); anxiety and depression (HADS), self-efficacy (modified Self-efficacy Scale), health status (EQ-5D) and satisfaction with care (questions developed for study). A single reminder was sent to non-responders after three weeks. Data were analysed by age, co-morbidities, and treatment group.

Results

316 men completed questionnaires (64.1% response rate). Overall satisfaction with follow-up care was high, but was lower for psychosocial than physical aspects of care. Urinary, bowel, and sexual functioning was reported as a moderate/big problem in the last month for 15.2% (*n* = 48), 5.1% (*n* = 16), and 36.5% (*n* = 105) men, respectively. The most commonly reported moderate/high unmet needs related to changes in sexual feelings/relationships, managing fear of recurrence/uncertainty, and concerns about the worries of significant others. It was found that 17% of men (n = 51/307) reported potentially moderate to severe levels of anxiety and 10.2% reported moderate to severe levels of depression (n = 32/308). The presence of problematic side-effects was associated with higher psychological morbidity, poorer self-efficacy, greater unmet needs, and poorer overall health status.

Conclusion

While some men report relatively few problems following prostate cancer treatment, this study highlights important physical and psycho-social issues for a significant minority of prostate cancer survivors. Strategies for identifying those men with on-going problems, alongside new interventions and models of care, tailored to individual needs, are needed to improve quality of life. Key words: **Prostate cancer; follow-up care; survivors; Quality of Life; primary care**

Introduction

Prostate cancer is the commonest non-dermatological cancer in men in the Western world. In 2011 there were 41,736 new cases in the UK, and over 10,000 deaths [1]. Although it represents the second commonest cause of death from cancer, improvements in early detection and treatment strategies has resulted in a global improvement in survival statistics, more marked in economically developed nations [1] [2]. Treatments for localised disease include radical prostatectomy, external beam radiotherapy, and brachytherapy, often with androgen deprivation therapy. Active surveillance is offered to men whose disease is considered clinically insignificant for them at the time of diagnosis, with regular re-assessment of disease and patient factors to determine if and when a need for radical therapy arises; its underlying premise is to avoid or delay. Locally advanced disease is typically managed with radiotherapy plus androgen deprivation therapy, with some proponents offering surgery as part of multimodal therapy[3], whereas metastatic prostate cancer is usually managed by initial androgen deprivation therapy alone [4].

Over and above regular PSA monitoring for the detection of recurrence, it is recognised that prostate cancer patients can have a wide range of follow-up needs including the management of both physical and psycho-social side-effects of diagnosis and treatment [5] [6]. However, a recent survey conducted by Prostate Cancer UK reported that over a quarter of men felt that the provision of good quality information and support was not adequate for their needs, and almost one-third reported follow-up care was not sufficient in terms of addressing the side-effects of treatment [7]. Previous studies have also highlighted supportive care needs [8, 9] and shortcomings with existing follow-up services [10] in this patient population.

The increase in demand for follow-up care is placing a significant strain on hospital outpatient clinics. To resolve this, it has been suggested that primary care could play a larger role in cancer follow-up [11]. NICE currently recommends a move to follow-up outside of the hospital setting for prostate cancer patients who are stable at 24 months post-diagnosis [12], although findings from a recent audit indicate that specialist MDTs in England currently expect approximately 30% of prostate cancer

patients with low-risk disease who receive radical treatment to be followed up for longer than 5 years, despite the low risk of relapse [13]. This audit report also recommends that the availability of personal support services including cancer advisory centres, sexual function and continence advice, and psychological counselling should be improved [13]. The American Cancer Society have recently published their guidelines advocating that follow up care should be provided in the primary care setting soon after hospital treatment finishes [14].

The survey reported herein was conducted as the first phase of a larger study developing and pilot testing a nurse-led psycho-educational intervention delivered to men in primary care (PROSPECTIV) [15]. In a sample of UK men with prostate cancer who had completed initial treatment and were living with stable disease, we assessed: 1) symptoms experienced and the extent to which men found these bothersome; 2) unmet needs; 3) psychological morbidity; 4) self-efficacy; 5) satisfaction with care and 6) overall health status, with a view to informing new models of follow-up. We collected this information as a baseline measure of quality of life outcomes against which to compare the findings of our future intervention study, and to inform the development of alternative models of follow-up.

Subjects/Patients and Methods

Recruitment

Men were recruited to the study from two cancer centres in the UK (Oxford University Hospitals NHS Trust and Cambridge University Hospitals NHS Foundation Trust). We sought to invite all men diagnosed 9-24 months previously, regardless of treatment modality, whose condition was considered stable as judged by the most recent prostate specific antigen (PSA) test result. We selected nine months post-diagnosis as the time when most radical treatments would have been completed. We used the following criteria as an indication of stable disease: surgical patients - PSA $\leq$ 0.2 ng/ml; radiotherapy (brachytherapy or external beam) patients: PSA $\leq$ 2 ng/ml; hormone therapy patients: PSA $\leq$ 10 ng/ml. Eligible men were identified from clinic databases and clinic patient records.

546 men were sent an invitation to participate, signed by a consultant from their hospital team. The invitation included a patient information sheet, a self-completion questionnaire, and a reply paid envelope. A single reminder was sent to non-responders after three weeks.

Questionnaire

The questionnaire (Appendix 1), which was designed to assess men's follow-up care and post-diagnosis and treatment quality of life, measured: clinical details; satisfaction with follow-up care (questions developed for the study); prostate-related quality of life; unmet needs; psychological well-being; self-efficacy; co-morbidities; health status; and standard socio-demographic details. Wherever possible, existing validated scales were used (see below).

Prostate-related quality of life

Prostate related quality of life was measured using the Expanded Prostate Cancer Index Composite - 26 item version (EPIC-26), which is a brief, valid and reliable subjective measure of health quality among patients with prostate cancer [16]. The measure comprises 26 items across the following 5 domains: urinary incontinence; urinary irritation/obstruction; bowel function; sexual and vitality functions; hormonal disturbance. As well as measuring functioning in each of the domains, the measure also assesses the extent to which functioning is perceived to be a problem by the patient.

Unmet Needs

The Supportive Care Needs Survey 34 item version (SCNS- SF34) assesses respondents' current level of need across the following domains: psychological, health system and information, physical and daily activity, patient care, and support and sexuality. Need is rated on a 5 point scale ranging from no need to high need (1 = no need, 2 = need was satisfied, 3 = low need, 4 = moderate need, 5 = high need) [17]. This validated instrument has been previously used in cancer survivorship studies [18].

Psychological Wellbeing

Psychological wellbeing was assessed using the Hospital Anxiety and Depression Scale (HADS) [19]. The HADS is a validated and widely used, 14-item screening instrument for assessing levels of anxiety and depression in patients. Each item is scored from 0-3. The anxiety and depression sub-scores are both on scales of 0-21. Scores of 8-10 on either sub-scale indicate possible cases, and scores of ≥11 indicate probable cases. The HADS has also previously been used in studies of cancer survivors [20].

Self-Efficacy

The Self-Efficacy for Managing Chronic Disease Scale [21] was developed to measure self-efficacy in people with chronic conditions and has also been used with cancer patients[22]. Respondents rate their confidence to perform six self-management behaviours (1 = 'not at all confident' to 10 = 'totally confident'). A mean score is calculated (range 1 to 10) with a high score indicating high self-efficacy. Following the method of Foster *et al.*[22], we added 5 cancer-specific self-management behaviours using the same rating scale and calculated a mean score (range 1–10). This new Cancer Survivors Self Efficacy Scale of 11 items has been shown to form a strongly homogenous, uni-dimensional scale of

self-efficacy (H = 0.54) with excellent reliability (alpha = 0.92)[22].

Health Status

The EQ-5D-5L was used as a measure of health status [23]. A crosswalk algorithm was used to convert the 5L EQ5D to the 3L version[24]. Each of the five dimensions in the EQ-5D (mobility, self-care, activities, pain/discomfort, and anxiety/depression) is scored from 1 (no problem) to 3 (extreme problem), generating a profile (e.g. 11232) that can be used to calculate a single index score (range: 0.04 to 1.000). The EQ-5D also generates a self-rating of health-related quality of life scored from 0 to 100 on a visual analogue scale (VAS).

Satisfaction with Care

As we were unable to find any suitable, previously validated measures, satisfaction with care was measured using 5 questions developed for this study. User representatives were involved in developing and pilot testing the questions which asked participants to rate, on a 5-point Likert scale ranging from 'not at all satisfied (score =1)' to 'totally satisfied (score=5)', how well their follow up care had addressed any a) physical problems / symptoms b) emotional/psychological problems c) relationship problems d) social problems. A final item asked participants to rate their overall satisfaction with general support and care, using the same Likert scale. Items were analysed individually.

Statistical analysis

Data analysis was undertaken using SPSS software version 22.0. Descriptive statistics were produced, using medians and inter-quartile ranges instead of means and standard deviations in cases of heavily skewed data. The standardised questionnaires were analysed and missing data handled in accordance with their respective guidelines. Associations between the reporting of moderate or large problems according to the EPIC questions and other measures included in the questionnaire were explored. In addition, sub-group analyses based on age (≤65 years *vs* 66+), co-morbidities (0 *vs* 1 *vs* >1), and treatment group were carried out. Statistical significance tests were only carried out if clinically significant differences were observed. Independent samples t-tests were used to compare means, and the non-parametric equivalent was used to compare medians in the case of skewed data. Proportions were compared using the chi-square test. Associations could not be explored using multivariate regression analyses due to limitations in the sample size, particularly in terms of the low numbers within each treatment group.

Results

Recruitment and sample characteristics

546 questionnaires were posted and 369 completed questionnaires were returned. Of these, 53 were excluded because the date of diagnosis given by the respondent on the questionnaire was outside our inclusion criteria, leaving a total of 316 responses from a potentially eligible population of 493 (response rate = 64.1%). There was no significant difference between respondents and non-respondents by age, time since diagnosis, and recruitment centre. Sample demographics and clinical characteristics are presented in Table 1. The mean age of the sample was 67.8 years (SD = 7.6 years; range 46-88 years), most were married (*n* = 275; 89%), and the overwhelming majority were White British (*n* = 292; 95%).

At the time of completing the survey, the average time since initial diagnosis was 17.1 months (SD = 4.5). Just over a third of patients had undergone surgery (*n* = 115; 37%) or radiotherapy (*n* = 117; 37%) as their primary treatment for prostate cancer, with the majority of those undergoing radiotherapy also receiving adjuvant hormone therapy (*n* = 81; 26%). Other primary treatment methods included brachytherapy (*n* = 17; 5%), hormone therapy only (*n* = 36; 11%), and active surveillance (*n* = 43; 14%). Four patients did not provide their treatment details. Two-thirds of respondents (*n* = 205; 65%) had at least one co-morbidity.

Current care and satisfaction with care

The mean time between participants' last and next outpatient appointment was 6.6 months (SD = 3.6 months), with just over half either usually or always seeing the same person (n = 191; 61%). Around half (*n* = 171/315; 54%) saw a consultant at their last out-patient appointment, a quarter saw a doctor other than a consultant (*n* = 73/315; 23%), and a fifth saw a nurse (*n* = 62/315; 20%). Respondents reported a mean journey length of 43 minutes (SD = 23 minutes) to their last out-patient appointment, and a median wait time of 20 minutes (IQR = 10-30 minutes). The mean length of their last consultation was 14 minutes (SD = 7 minutes). Very few reported having a regular follow-up schedule set-up with their GP (*n* = 6; 2%), with the majority only interacting with their GP to get PSA test results (*n* = 195; 62%).

Patients reported high levels of overall satisfaction with the support and care they had received (median score = 5, IQR: 4-5). Satisfaction was, however, lower in relation to how well emotional/psychological problems (median score=4, IQR: 3-5), relationship (median score = 4, IQR: 3-5) and social problems (median score = 4, IQR: 3-5) had been addressed, compared to physical problems (median score = 5, IQR: 4-5).

Patient-reported symptoms

Table 2 presents symptoms experienced in the past four weeks as measured by the EPIC-26, broken down by primary treatment received. EPIC domain summary scores are also reported. Figure 1 presents the degree to which men reported urinary, bowel, and sexual functioning and hormone-related issues to be a problem to them in the past month.

One in ten respondents (30/315; 10%) missed out the question relating to overall sexual function entirely, with many indicating in the open ended text box provided that they perceived the question to be irrelevant to their current situation. Of those that did answer, around three-quarters (*n* = 233/285; 82%) reported that their overall sexual function had been poor in the last four weeks. Around half (*n* = 107/233; 46%) of those reporting poor overall sexual function considered this to be a moderate or big problem for them over the past month. Of those, less than half (*n* = 47/107; 44%) had discussed this issue at their most recent outpatient appointment, while 16% (*n* = 17/107) had previously been referred to a specialist for this reason. Nearly all were married or cohabiting with a partner (*n* = 105/107; 98.1%), but there was no significant correlation with age. Sexual function was a moderate/big problem mostly among those who had hormone therapy (with or without radiotherapy) as a primary treatment (*n* = 99/102; $p<0.0001$).

Urinary and bowel functioning was considered a moderate/big problem over the last month by 15.2% (*n* = 48/315) and 5.1% (*n* = 16), respectively. The main symptoms relating to urinary function were general incontinence issues such as urinary control and leaking, in addition to the need to urinate frequently. Of those who reported their urinary or bowel function was a moderate or big problem to them, 31% (*n* = 15/48) and 38% (*n* = 6/16) respectively had previously been referred to a specialist. The symptoms reported for both urinary and bowel function correlated well with the extent to which the patient perceived this issue to be a problem for them. There were no notable differences across treatment groups in terms of prevalence of urinary function problems, but bowel function problems were most common among those who had undergone radiotherapy in combination with hormone treatment. Of those reporting a moderate/big problem with their urinary or bowel function, 73% (*n* = 35/48) and 63% (*n* = 10/16) respectively had discussed the problem at their last outpatient appointment.

For hot flushes, lack of energy and change in body weight the comparable proportions were 19.1%, 20% and 13%, whereas for feeling depressed and breast tenderness, the proportions were much lower (7% and 2.8% respectively).

Health status

Overall health status, measured using the EQ-5D-5L, was comparable, if not better than population norms [25, 26], with an overall mean index score of 0.852 (SD = 0.173) and an overall mean VAS score of 79.73 (SD = 16.20). Mean index scores were significantly lower for those reporting moderate/big problems with their bowel or urinary function, but those with equivalent sexual function problems did not present with significantly lower scores (see Table 4).

Unmet needs

Table 3 presents the most commonly reported unmet needs. The most prevalent unmet needs related to sexual issues, concerns about significant others, and anxieties around the possibility of recurrence.

On average, those reporting overall urinary and bowel function as a moderate/big problem for them had a significantly greater number of unmet needs (urinary: 11.44 *vs* 4.84; $p < 0.001$; bowel: 16.44 *vs* 5.37; $p < 0.001$). This was also the case for sexual function (9.27 *vs* 4.11, $p < 0.001$).

Psychological well-being

The proportion of possible or probable cases of clinical anxiety and depression (anxiety: *n* = 51/307; 17%; depression: *n* = 32/308; 10%) were no higher those reported for the general population [27]. The proportions of possible/probable cases of anxiety and depression were significantly larger among those reporting moderate or large symptom problems. Of the possible or probable cases of clinical anxiety or depression, 12% (*n* = 6/51) and 16% (*n* = 5/32) respectively had been referred to specialist for this reason. Overall, only 5% (*n* = 17/315) had been referred to a specialist for anxiety or depression problems.

Those with more than one co-morbidity were significantly more likely to have possible/probable clinical levels of anxiety and depression compared to those with no co-morbidities (anxiety: 28.8% *vs* 9.4%; $p<0.001$; depression: 21.9% *vs* 4.7%; $p<0.001$).

Self-efficacy

Responses on the modified self-efficacy scale were generally high, with a median confidence score of at least eight obtained across all activities (where 1 = not at all confident and 10 = totally confident). Respondents reported being generally confident with their ability to keep fatigue, physical discomfort, emotional distress or any other symptoms or health problems from interfering with the things they want to do. In relation to cancer specifically, respondents were also generally confident they could access information and support, deal with problems the cancer may have caused, and contact their doctor with any problems. Those with moderate/large symptom problems reported

lower scores on average across all of the self-efficacy questions (some significantly lower), although for the most part the reduction was by less than one point on the 10-point scale.

Discussion

This study enriches our knowledge of the issues that are important to prostate cancer survivors within 2 years of diagnosis in the UK. It both confirms and extends the previous work of Glaser *et al*. [5] and Ream *et al*. [6] and describes the level of symptoms, unmet need, and psychological well-being in men with stable disease. Our study also presents new and important information on the extent to which men in the UK find ongoing symptoms to be bothersome, levels of satisfaction with current follow-up care, and mens confidence to self-manage problems that arise.

We report significant variation in the types and scale of issues experienced by men. Overall, the picture is a fairly encouraging one, with many men experiencing relatively few problems in the post-treatment phase, and reporting high levels of satisfaction with the follow-up care they have received. However, whilst these findings may well be a true reflection, the challenges of accurately measuring patient satisfaction, and the reluctance of patients to criticise the care they have received have been previously noted in the literature [28]. Ongoing symptoms were present in a significant proportion of the men in our study, particularly in relation to sexual functioning and, to a lesser degree, urinary and bowel functioning. Problems with fatigue, weight gain and hot flushes, often associated with hormone therapy, were also reported. For some men, these issues are not considered bothersome, and intervention may not be necessary, whereas for others they can have a very significant impact on quality of life, potentially affecting relationships and social activities, and leading to or contributing to anxiety and depression.

Many of the problems men are experiencing can potentially be lessened by relatively simple interventions, and a recent review concluded that promoting self-management in men with prostate cancer is an effective strategy [29]. For example, pelvic floor exercises, bladder retraining, monitoring fluid intake and avoiding alcohol and caffeine can positively influence troublesome urinary symptoms [12]. In some instances, treatment with drugs will also be indicated. Similarly, dietary changes and pelvic floor exercises can have a positive impact on bowel problems. In cases where symptoms cannot be improved, properly assessing incontinence and appropriate use of continence aids may improve quality of life. For hot flushes, in addition to the promotion of self-management strategies such as cotton clothing and avoiding hot drinks, evidence also supports the use of pharmacological interventions [30].

For men with sexual dysfunction, patient education and appropriate prescribing of PDE5 inhibitors, or where that fails, use of medicated urethral system for erections (MUSE), vacuum pumps or intra-

cavernous injections may be helpful for enhancing sexual function [31-33]. However, it is often not possible to fully resolve treatment-related sexual dysfunction and, in those cases, it may be appropriate to offer the patient (and partner if appropriate) counselling and support to come to terms with this, and to find new ways of fulfilling intimacy [32, 34, 35]. It is of note that we found men were more likely to discuss urinary/ bowel problems than sexual problems at follow-up appointments. It is important that health professionals learn ways to facilitate conversations about sexual issues, regardless of the age of the patient.

Strengths of this study include: assessment of over 300 men who had a range of different prostate cancer treatments; participants from two large geographical areas of the UK – Thames Valley and the Eastern Counties (Cambridgeshire, Bedfordshire, and Suffolk); and a relatively high response rate. However, although we found that there was no significant difference between respondents and non-respondents by age, time since diagnosis, and recruitment centre, volunteer bias cannot be excluded. Those with the greatest need may be less or more likely to participate in such a study. It may also be that the two areas included in the study are not representative of the wider UK population, although our sample is similar in terms of mean age and proportion with university degree to that reported in a large study which recruited men with prostate cancer from 66 cancer facilities across England [18]. The cross-sectional nature of our study also means we cannot infer causality between prostate cancer treatment and the symptoms reported by men. However, previous population-based studies have included age-matched controls and have found elevated levels of the symptoms described in this paper in men with prostate cancer[36]. Finally, whilst we sought to include the most relevant and valid measures available in our questionnaire, it is possible that alternative measures may have captured different outcomes of relevance to prostate cancer survivors.

In conclusion, this survey of men in the UK has shed new light on the experiences of prostate cancer survivors in the post-treatment phase. Our findings suggest that many men are doing relatively well, but with important physical and psycho-social effects occurring in a significant minority. Methods for risk stratification and identification of those men with on-going problems [37], alongside new interventions and models of care which are tailored to individual needs are needed to improve quality of life. We suggest that primary care practitioners have many of the necessary skills to address the issues that we have identified as being of importance to prostate cancer survivors. If methods are developed to stratify which prostate cancer survivors are at low risk of problems, and primary care practitioners are provided with some prostate cancer-specific education – particularly in relation to psycho-sexual aspects of prostate cancer, we suggest that primary care could be well placed to play a greater role in prostate cancer follow-up. An initial assessment by the treating

hospital clinician post-treatment could identify which men need further hospital-based care and which can be safely and well managed in primary care. Blood tests for the monitoring of PSA levels, and regular delivery of hormonal therapy injections, are already overseen in the primary care setting. This regular contact in a local, familiar environment may present an ideal opportunity to provide more generalised follow-up support to men, and to complement hospital-based care. Previous studies have however highlighted that education, adequate resourcing, fool-proof systems for surveillance, and easy access back to secondary care when required are key to the success of increased primary care involvement in cancer follow-up care[38]. Further research is required to find the most effective and cost-effective ways to deliver follow-up care which maximises quality of life for prostate cancer survivors. Given that men in this study have reported high levels of satisfaction with current, largely hospital-led, follow-up care, it is important secondary and primary care health professionals work together with patients to come up with cost-effective models that are acceptable to all.

Ethics:

Ethical permission was obtained from Oxford Research Ethics Committee A, reference no.12 SC 0500

Authorship and conflict of interest statement:

EW, PR, DW, RN, CC, CW conceived of the study. All authors contributed to the development of the study, EW is the grant-holder. DN, CK, FH, and PS advised on recruitment from secondary care sites. RP provided guidance on sample size and is leading statistical analyses for the study. JW advised on data requirement for health economics. HB and MM provided user input to the design, study information and questionnaires. EF managed recruitment and study data. BS undertook the statistical analysis. EW and BS drafted the manuscript and all other authors provided comments and approved the final version. No competing interests were declared.

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Table 1. Patient demographics and disease characteristics

Variable/characteristic (Total *N* = 315)	Median	Inter-quartile Range
Patient age (years) (*n* = 293)	68	64-81
Time since diagnosis (months) (*n* = 315)	17	14-25
Marital Status	***n***	**%**
Single	6	1.9
Married/Cohabiting	275	89.0
Widowed	12	3.9
Divorced/Separated	9	2.9
Other	7	2.3
Total	309*	
Employment Status	***n***	**%**
In paid work	107	34.6
Temporarily off sick	1	0.3
Unemployed	3	1.0
Retired	189	61.2
Long-term disability or ill health	4	1.3
Full-time education, training or work experience	0	0.0
Other	5	1.6
Total	308*	
Ethnicity	***n***	**%**
White British	292	94.8
White - Other	11	3.6
Black - other	1	0.3
Chinese	1	0.3
Other	3	1.0
Total	308*	
Educational Status	***n***	**%**
O Level/GCSE	50	16.7
A Level	19	6.4
Clerical or commercial qualification	32	10.7
College or university degree	64	21.4
Postgraduate qualification	40	13.4
None of these	94	31.4
Total	299*	
Co-morbidity	***n***	**%**
Heart problems	35	11.1
High Blood Pressure	118	37.5
Chronic obstructive pulmonary disease	8	2.5
Asthma	22	7.0
Diabetes	29	9.2
Arthritis	44	14.0
Osteoporosis	2	0.6
Inflammatory Bowel Disease	3	1.0
Other	51	16.2
At least one co-morbidity	205	65.1
No co-morbidities	110	34.9
Previous treatment**	***n***	**%**
Surgery	115	36.5
Radiotherapy – external beam	125	39.7
Brachytherapy – implanted radioactive seeds	17	5.4
Hormone	138	43.8
Active Surveillance	86	27.3
Other	8	2.5

* Total excludes missing data** Some men had received more than one type of treatment

Table 2 Symptoms experienced in previous 4 weeks, by treatment type

	All *N* =315	Surgery *n* = 115	Radiotherapy *n* = 36	Radiotherapy with adjuvant hormone therapy *n*= 81	Primary hormone therapy *n* = 36	Active surveillance *n* = 43	P-value
Urinary Function							
Incontinence							
Leaking >1 time/day	31/309 (10%)	23 (21%)	2 (6%)	3 (4%)	2 (6%)	1 (2%)	
Frequent dribbling	14/310 (5%)	7 (6%)	1 (3%)	5 (6%)	1 (3%)	0 (0%)	
Any pad use	33/301 (11%)	25 (22%)	1 (3%)	3 (4%)	2 (6%)	2 (5%)	
Leaking problem*	23/287 (8%)	13 (12%)	2 (7%)	5 (7%)	0 (0%)	3 (8%)	
Overall Domain Score** (n = 268)	94 (73-100)	86 (67-100)	100 (79-100)	100 (78-100)	100 (86-100)	93.8 (86-100)	0.039
*Irritation/obstruction**							
Dysuria	2/276 (1%)	0 (0%)	0 (0%)	1 (1%)	1 (3%)	0 (0%)	
Haematuria	1/275 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	
Weak stream	35/283 (12%)	8 (7%)	4 (15%)	10 (14%)	5 (16%)	8 (23%)	
Frequency	50/293 (17%)	17 (15%)	7 (23%)	13 (17%)	5 (15%)	7 (19%)	
Overall Domain Score** (n = 260)	94 (81-100)	94 (88-100)	88 (81-94)	88 (75-100)	88 (81-100)	88 (75-100)	
Overall Urinary Problem*	48/309 (16%)	16 (14%)	6 (17%)	13 (17%)	5 (14%)	7 (17%)	0.087
Bowel function							
Urgency*	21/302 (7%)	3 (3%)	2 (6%)	12 (15%)	2 (6%)	1 (3%)	
Frequency*	19/286 (7%)	4 (4%)	2 (7%)	12 (16%)	0 (0%)	0 (0%)	
Incontinence*	9/287 (3%)	1 (1%)	2 (7%)	4 (5%)	1 (3%)	0 (0%)	
Bloody stools*	8/283 (3%)	2 (2%)	1 (4%)	5 (7%)	0 (0%)	0 (0%)	
Rectal pain*	9/287 (3%)	5 (5%)	0 (0%)	3 (4%)	0 (0%)	1 (3%)	
Overall Domain Score** (n = 277)	100 (92-100)	100 (96-100)	92 (83-100)	94 (79-100)	100 (96-100)	100 (96-100)	-
Overall Bowel Problem*	16/311 (5%)	4 (3%)	1 (3%)	10 (13%)	0 (0%)	0 (0%)	
Sexual function							
Poor erections	233/289 (81%)	93 (83%)	22 (73%)	70 (93%)	29 (94%)	16 (43%)	
Orgasm difficulty	201/275 (73%)	70 (64%)	21 (72%)	64 (90%)	27 (100%)	17 (49%)	
Erections not firm***	248/289 (86%)	97 (87%)	24 (80%)	71 (95%)	30 (97%)	23 (61%)	
Erections not reliable***	222/274 (81%)	94 (87%)	23 (77%)	66 (96%)	27 (100%)	17 (47%)	
Poor sexual function	233/285 (82%)	90 (81%)	22 (73%)	70 (96%)	29 (100%)	19 (50%)	
Overall Domain Score** (n = 271)	17 (4-32)	16.7 (4-36)	13.8 (0-43)	12.5 (4-17)	16.7 (8-17)	57 (13-88)	0.000
Overall Sexual Function*	115/289 (40%)	54 (47%)	12 (39%)	28 (38%)	9 (27%)	11 (30%)	
Vitality/hormonal function*							
Hot flushes	60/295 (20%)	14 (13%)	7 (23%)	28 (37%)	9 (26%)	2 (5%)	
Breast Tenderness	9/278 (3%)	3 (3%)	2 (8%)	4 (6%)	0 (0%)	0 (0%)	
Depression	22/285 (8%)	8 (7%)	1 (4%)	8 (11%)	5 (16%)	0 (0%)	
Lack of energy	63/297 (21%)	14 (13%)	6 (19%)	28 (36%)	10 (29%)	5 (13%)	
Weight gain	41/287 (14%)	10 (9%)	4 (14%)	17 (23%)	6 (18%)	4 (12%)	
Overall Domain Score** (n = 273)	90 (75-100)	95 (85-100)	95 (70-100)	75 (55-90)	78 (68-90)	95 (90-100)	0.000

*Responses were dichotomised to only include moderate or big problems. **Domain scores out of 100, where 100=best possible score. Medians and interquartile ranges reported. ***Categorised as 'erections not firm' if respondents stated that their erections were not firm enough for intercourse. Categorised as 'erections not reliable' if respondent could not achieve erections more than half the time when desired. Due to heavily skewed data, p-values for domain scores were produced using a non-parametric test which compares medians across groups.

Table 3: Most common unmet needs (low/moderate/high)

	Not Applicable	Need was satisfied	Low need	Moderate need	High need
	N (%)	N (%)	N (%)	N (%)	N (%)
Pain (n=308)	264 (86%)	20 (6%)	14 (5%)	5 (2%)	5 (2%)
Lack of Energy (n=304)	207 (67%)	36 (12%)	30 (10%)	21 (7%)	10 (3%)
Feeling unwell a lot of the time (n=306)	259 (84%)	16 (5%)	21 (7%)	9 (3%)	1 (0%)
Work around the home (n=306)	250 (81%)	24 (8%)	21 (7%)	10 (3%)	1 (0%)
Not being able to do the things you used to do (n=309)	225 (73%)	28 (9%)	26 (8%)	21 (7%)	9 (3%)
Anxiety (n=306)	227 (74%)	26 (8%)	30 (10%)	16 (5%)	7 (2%)
Feeling down or depressed (n=309)	226 (73%)	22 (7%)	37 (12%)	16 (5%)	8 (3%)
Feelings of sadness (n=307)	224 (73%)	27 (9%)	32 (10%)	18 (6%)	6 (2%)
Fears about the cancer spreading (n=309)	152 (49%)	60 (19%)	60 (19%)	26 (8%)	11 (4%)
Worry that the results of treatment are beyond your control (n=304)	187 (61%)	45 (15%)	42 (14%)	25 (8%)	5 (2%)
Uncertainty about the future (n=306)	171 (56%)	37 (12%)	62 (20%)	30 (10%)	6 (2%)
Learning to feel in control of your situation (n=306)	194 (63%)	44 (14%)	52 (17%)	12 (4%)	4 (1%)
Keeping a positive outlook (n=306)	212 (69%)	44 (14%)	37 (12%)	7 (2%)	6 (2%)
Feelings about death and dying (n=307)	218 (71%)	36 (12%)	33 (11%)	12 (4%)	8 (3%)
Changes in sexual feelings (n=303)	169 (55%)	33 (11%)	46 (15%)	35 (11%)	20 (6%)
Changes in your sexual relationships (n=303)	178 (58%)	34 (11%)	41 (13%)	30 (10%)	20 (6%)
Concern about the worries of those close to you (n=304)	154 (50%)	54 (18%)	48 (16%)	28 (9%)	20 (6%)
More choice about which cancer specialist you see (n=306)	245 (80%)	28 (9%)	21 (7%)	9 (3%)	3 (1%)
More choice about which hospital you attend (n=306)	252 (82%)	34 (11%)	12 (4%)	7 (2%)	1 (0%)
Reassurance by medical staff that the way you feel is normal (n=307)	202 (66%)	58 (19%)	28 (9%)	10 (3%)	9 (3%)
Hospital staff attending promptly to your physical needs (n=305)	225 (73%)	47 (15%)	13 (4%)	13 (4%)	7 (2%)
Hospital staff acknowledging and showing sensitivity to your feelings and emotional needs (n=306)	199 (65%)	71 (23%)	17 (6%)	12 (4%)	7 (2%)
Being given written information about the important aspects of your care (n=309)	190 (62%)	75 (24%)	24 (8%)	8 (3%)	12 (4%)
Being given information (written, diagrams, drawings) about aspects of managing your illness and side-effects at home (n=310)	194 (63%)	74 (24%)	18 (6%)	14 (5%)	10 (3%)
Being given explanations of those tests for which you would like explanations (n=307)	180 (58%)	81 (26%)	22 (7%)	10 (3%)	14 (5%)
Being adequately informed about the benefits and side-effects of treatments before you choose to have them (n=306)	175 (57%)	79 (26%)	22 (7%)	17 (6%)	13 (4%)
Being informed about your test results as soon as feasible (n=311)	147 (48%)	96 (31%)	29 (9%)	21 (7%)	18 (6%)
Being informed about cancer which is under control or diminishing (that is remission) (n=309)	179 (58%)	81 (26%)	21 (7%)	17 (6%)	11 (4%)
Being informed about things you can do to help yourself get well (n=308)	185 (60%)	62 (20%)	31 (10%)	20 (6%)	10 (3%)
Having access to professional counselling (eg, psychologist, social worker, counsellor, nurse specialist) if you, family or friends need it (n=310)	229 (74%)	38 (12%)	19 (6%)	14 (5%)	10 (3%)
Being given information about sexual relationships (n=308)	207 (67%)	35 (11%)	35 (11%)	15 (5%)	16 (5%)
Being treated like a person not just another case (n=309)	191 (62%)	82 (27%)	14 (5%)	9 (3%)	13 (4%)
Being treated in a hospital or clinic that is as physically pleasant as possible (n=310)	194 (63%)	88 (29%)	5 (2%)	13 (4%)	10 (3%)
Having one member of hospital staff who you can talk to about all aspects of your condition, treatment or follow-up (n=309)	178 (58%)	78 (25%)	25 (8%)	16 (5%)	12 (4%)

Table 4. Differences in mean EQ-5D-3L index score for those reporting moderate or large symptom problems

	No Moderate/Big Problem Mean (SD)	**Moderate/Big Problem Mean (SD)**	**P-value***
Urine Function	0.868 (0.160)	0.773 (0.222)	0.001
Bowel Function	0.862 (0.166)	0.653 (0.195)	0.000
Sexual Function	0.861 (0.176)	0.838 (0.170)	0.261

*P-values were calculated using a 2-group independent samples t-test.